UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/627,408	07/25/2003	Manikkam Suthanthiran	955-10 P/CON/DIV	2823

23869 7590 05/03/2007
HOFFMANN & BARON, LLP
6900 JERICHO TURNPIKE
SYOSSET, NY 11791

EXAMINER	
FETTEROLF, BRANDON J	

ART UNIT	PAPER NUMBER
1642	

MAIL DATE	DELIVERY MODE
05/03/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/627,408	SUTHANTHIRAN ET AL.	
	Examiner	Art Unit	
	Brandon J. Fetterolf, PhD	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 February 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1 and 3-13* is/are pending in the application.

4a) Of the above claim(s) *3-12* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1 and 13* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to the Amendment

The Amendment filed on 02/24/2005 in response to the previous Non-Final Office Action (10/20/2004) is acknowledged and has been entered.

Claims 1 and 3-13 are currently pending.

Claims 3-12 are withdrawn from consideration as being drawn to non-elected inventions.

Claims 1 and 13 are currently under consideration.

Rejections Withdrawn:

The rejection of Claims 1-2 and 13-14 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement is withdrawn in view of Applicants amendments/arguments.

The rejection of claims 1-2 and 13-14 under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method for reducing formation, progression or metastasis of a neoplasm in a mammal, comprising administering the mammal with an effective amount of a angiotensin II inhibitor, does not reasonably provide enablement for a method of preventing formation, progression or metastasis of a neoplasm in a mammal, comprising administering an effective amount of a angiotensin II inhibitor is withdrawn in view of Applicants amendments/arguments.

The rejections of claims 1-2 and 13 are rejected under 35 U.S.C. 102(b) as being anticipated by Olga et al. (J. Clin. Invest. 1996; 98: 671-679, *IDS*) or Dudley et al. (US 5,444,069, 1995) or Ashton et al. (WO 92/20661, 1992) are withdrawn in view of Applicants amendments/arguments. In particular, the prior art does not teach that the compounds are angiotensin II receptor type AT1 antagonist. .

Rejections Maintained:

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1 and 13 remain rejected under 35 U.S.C. 102(b) as being anticipated by Griswold et al. (US 5,824,696, 1998).

(Note: The Examiner appreciates Applicants for pointing out US 5,824,696 referred to as Edgar et al. in the previous office action is really Griswold et al. which is reflected in the current office action)

Griswold et al. teach a method of treating chronic inflammatory disease states in a mammal, especially a human, comprising administering an effective amount of an angiotensin II receptor antagonist (column 1, lines 66 to column 2, line 1). Specifically, the patent teaches a method of treating disorders such as tumor growth, i.e., neoplastic transformation and growth/metastasis (column 2, lines 6-12). With regards to the angiotensin II receptor antagonist, the patent teaches that angiotensin antagonists include, but are not limited to, the AT1 antagonist losartan (column 3, lines 14-17).

In response to this rejection, Applicants assert that Griswold et al. teaches the treatment of chronic inflammatory condition and, does not teach a method of treating disorders such as tumor growth. In particular, Applicants assert that the teachings at column 2, lines 6-12 states are mere speculation that tumor growth in human may be treated and constitutes a suggestion to try which is insufficient to constitute a disclosure that renders a method recited in a patent claim unpatentable. Therefore, Applicants assert that Griswold et al. reference is an improper prior art reference in supports of an obviousness rejection because this speculation constitutes no more than a potential promising field of experimentation, and meets the "obvious to try" standard of MPEP 2145.

These arguments have been carefully considered, but are not found persuasive.

In the instant case, the Examiner acknowledge that Applicants assert that the teachings of the prior art meets the "obvious to try" standard of MPEP 2145. However, the Examiner

recognizes that these assertions do not appear to be commensurate in scope with the instant rejection which is an anticipation rejection under 35 USC 102 (b) and not a obviousness rejection under 103. In other words, the Examiner recognizes that Griswold et al. teach a method of treating disorders such as tumor growth, i.e., neoplastic transformation and growth/metastasis (column 2, lines 6-12). As such, Griswold et al. anticipates the currently amended claims.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1 and 13 remain rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-3, 5-8 and 10 of U.S. Patent No. 6,641,811.

Although the conflicting claims are not identical, they are not patentably distinct from each other because the method for reducing formation, progression or metastasis of a neoplasm in conjunction with immnosuppressive therapy in a mammal in need thereof, comprising treating the mammal with an effective amount of an angiotensin II receptor blocker claimed in the conflicting patent appears to fall with in the same scope of a method for reducing formation, progression or metastasis of a neoplasm, comprising administering an effective amount of an angiotensin II receptor type II AT1 antagonist, claimed in the instant application.

Note: The transitional term "comprising" recited in the currently pending claims, which is synonymous with "including," "containing," or "characterized by," is inclusive or open-ended and does not exclude additional, unrecited elements or method steps.

In response to this rejection, Applicants assert that this rejection will be addressed with a terminal disclaimer, if appropriate, upon notification of patentable subject matter in the present application.

These arguments have been carefully considered, but are not found persuasive.

As stated above, although the conflicting claims are not identical, they are not patentably distinct from each other because the method claimed in the conflicting patent appears to fall within the same scope of the method claimed in the instant application.

All other rejections and/or objections are withdrawn in view of applicant's amendments and arguments there to.

Conclusion

Therefore, NO claim is allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brandon J. Fetterolf, PhD whose telephone number is (571)-272-2919. The examiner can normally be reached on Monday through Friday from 7:30 to 4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shanon Foley can be reached on 571-272-0898. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Brandon J Fetterolf, PhD
Patent Examiner
Art Unit 1642

BF

SHANON FOLEY
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600